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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,635	10/25/2000	Kestutis Tautvydas	11536-001001/55190USA8A	4398

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EXAMINER
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JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/14/2003

*28*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/696,635

Applicant(s)

TAUTVYDAS ET AL.

Examiner

Shaojia A Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21,25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 4, 2003 has been entered in Paper No. 22.

This Office Action is a response to Applicant's request for continued examination (RCE) filed September 4, 2003 in Paper No. 22, and amendment and response to the Final Office Action (mailed January 29, 2003), filed September 4, 2003 in Paper No. 23 wherein claims 41-45 are newly submitted.

Currently, claims 31-45 are pending in this application.

Claims 31-45 are examined on the merits herein.

Applicant's declaration of Jeffrey F. Andrews (inventor) filed September 4, 2003 in Paper No. 24 under 37 CFR 1.132, is acknowledged and will be further discussed below.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. (5,460,833, of record) in view of Viccaro et al. (5,188,822, of record) and Carmody (5,145,685, of record).

Andrews et al. discloses an antimicrobial composition comprising (i) the instant fatty acid monoester such as glycerol monolaurate, propylene glycol monolaurate, glycerol and propylene glycol monoesters of caprylic and capric acids in amounts within the instant claim, (ii) the instant enhancers in amounts within the instant claim further comprising a chelating agent, EDTA, and the instant organic acid such as lactic acid, tartaric acid, adipic acid, succinic acid, citric acid, and all other instant acids, (iii) a food grade surfactant, anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; and a vehicle i.e., water and/or particular alcohols: propylene glycol and polyethylene glycol, or aqueous solution and ethanol (see abstract, col.2 lines 38-55, col.3 lines 1-8 and 35-38, col.4 lines 36-62, col.5 lines 4-13 and 20-39, and claims 1-9). Andrews et al. particularly discloses the components (i), (ii) and (iii) used together in the composition therein provide a synergistic antimicrobial activity, compared to used alone under the same condition (see col.2 lines 55-57 and col.3 lines 54-57). Hence, each of three major component alone is known to have antimicrobial activity. Andrews et al. also teaches that organic acids including the acids employed therein are known antimicrobial agents (see col.1 line 67 to col.2 line 7). Andrews et al. further discloses the

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compositions therein prepared by mixing the ingredients in the particular order (see col.5 lines 41 to col.6 line 5).

Andrews et al. do not expressly disclose the employment of the particular organic acid, benzoic acid or salicylic acid in their antimicrobial compositions.

Viccaro et al. discloses that benzoic acid is a known antimicrobial compound and useful in the oral (dental) composition therein, having antimicrobial activity (see col.1 and col.25, claim 11).

Carmody discloses that salicylic acid is a known antimicrobial agent and useful in the skin composition therein, having antimicrobial activity (see abstract, col.10-11, claims 2 and 12).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ of the particular organic acid benzoic acid or salicylic acid in the antimicrobial composition of Andrews et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ of the particular organic acid benzoic acid or salicylic acid in the antimicrobial composition of Andrews et al., since both benzoic acid and salicylic acid are known antimicrobial agents and also known to be useful in the antimicrobial compositions according to the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that employing or adding benzoic acid or salicylic acid, known useful for the same purpose, i.e., antimicrobial, in the antimicrobial composition of Andrews et al. would improve the antimicrobial effect and/or would produce additive effects for the composition of Andrews et al.

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Since all active composition components herein are known to useful in antimicrobial compositions, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Moreover, the disclosure of Andrews et al. in regard to combination of (i), (ii) and (iii) in the composition therein exerting a synergistic antimicrobial activity, has further provided the motivation for employing or adding the particular organic acid benzoic acid or salicylic acid, the known antimicrobial agents, in the antimicrobial composition of Andrews et al.

Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising the same composition because the preparation of a kit comprising containers containing ingredients of a composition is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, based on the preparation of the compositions disclosed by Andrews et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. (5,569,461, PTO-1449 submitted January 24, 2001) in view of Viccaro et al. (5,188,822, of record) and Carmody (5,145,685, of record).

Andrews et al. discloses an antimicrobial composition comprising (i) the instant fatty acid monoester such as propylene glycol monoesters of caprylic and capric acids in amounts within the instant claim, (ii) the instant enhancers in amounts within the instant claim further comprising a chelating agent, EDTA, and the instant organic acid such as lactic acid, tartaric acid, adipic acid, succinic acid, citric acid, and all other instant acids, (iii) anionic surfactants such as dioctyl sodium sulfosuccinate and sodium laurylsulfate; and a vehicle i.e., water and/or solvents miscible with water, particular alcohols: propylene glycol and polyethylene glycol, or aqueous solution, and fragrances (see abstract, col.2 lines 13-20, col.3 lines 1-56, col.4 lines 1-30, Examples at col.6, and claims 1-5). Andrews et al. particularly discloses the components (i), (ii) and (iii) used together in the composition therein provide surprisingly potent antimicrobial systems (see col. 13-19) and a synergistic antimicrobial activity, compared to used alone under the same condition (see col.2 lines 55-57 and col.3 lines 54-57). Hence, each of three major component alone is known to have antimicrobial activity. Andrews et al. also teaches that the organic acids including the acids employed therein are synergists as antimicrobial agents that may be used solely or in combination (see col.3 line 42-56). Andrews et al. further discloses the compositions therein prepared by mixing the ingredients in the order (see col.4 lines 52 to col.5 line 5).

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Andrews et al. do not expressly disclose the employment of the particular organic acid, benzoic acid or salicylic acid in their antimicrobial compositions.

Viccaro et al. discloses that benzoic acid is a known antimicrobial compound and useful in the oral (dental) composition therein, having antimicrobial activity (see col.1 and col.25, claim 11).

Carmody discloses that salicylic acid is a known antimicrobial agent and useful in the skin composition therein, having antimicrobial activity (see abstract, col.10-11, claims 2 and 12).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ of the particular organic acid benzoic acid or salicylic acid in the antimicrobial composition of Andrews et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ of the particular organic acid benzoic acid or salicylic acid in the antimicrobial composition of Andrews et al., since both benzoic acid and salicylic acid are known antimicrobial agents and also known to be useful in the antimicrobial compositions according to the prior art. Therefore, one of ordinary skill in the art would have reasonably expected that employing or adding benzoic acid or salicylic acid, known useful for the same purpose, i.e., antimicrobial, in the antimicrobial composition of Andrews et al. would improve the antimicrobial effect and/or would produce additive effects for the composition of Andrews et al.

Since all active composition components herein are known to useful in antimicrobial compositions, it is considered prima facie obvious to combine them into a



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single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Moreover, the disclosure of Andrews et al. in regard to combination of (i), (ii) and (iii) in the composition therein exerting a synergistic antimicrobial activity and organic acids employed therein as being synergists used solely or in combination, has further provided the motivation for employing or adding the particular organic acid benzoic acid or salicylic acid, the known antimicrobial agents, in the antimicrobial composition of Andrews et al.

Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising the same composition because the preparation of a kit comprising containers containing ingredients of a composition is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art, based on the preparation of the compositions disclosed by Andrews et al.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's remarks and the declaration of the inventor under 37 CFR 1.132 filed on September 4, 2003 in Paper No. 23 and 24 with respect to the rejection made under 35 U.S.C. 103(a) in the previous Office Action (January 29, 2003) have been fully

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considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art.

Again Applicant's assertions that there is no teaching or suggestion or in knowledge available generally to one skilled in the art that antimicrobial composition would retain the same antimicrobial activity in Andrews by substituting benzoic or salicylic acid and a reasonable expectation of success, and that secondary references do not cure the deficiencies of Andrews, have been considered but is not found persuasive. These remarks are believed to be adequately addressed by the obvious rejections presented above.

Additionally, Viccaro et al. (5,188,822) and Carmody (5,145,685) have been cited by the examiner primarily for their teachings that both benzoic acid and salicylic acid are known antimicrobial agents and also known to be useful in the antimicrobial compositions.

Therefore, motivation to combine the teachings of the prior art cited herein to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

The declaration of Andrews is insufficient to establish the fact that the claimed combination has any unexpected synergism as follows. First the declaration merely presents the comparable results among the compositions "A" comprising the combination of the monoester and salicylic acid, and "B" comprising combination of the monoester and benzoic acid, "C" comprising combination of the monoester and lactic acid, i.e., it is noted that all log reduction by all three compositions are merely

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comparable, and it is also noted even the log reduction by the water control is comparable to three composition. Secondly, these results appears generated from one shot, not from the statistic results. Thus, the accuracy and reliability are in question. Thirdly, the cited prior art 5,460,833, and 5,569,461 are not limited to one acid, lactic acid or alpha-hydroxy organic acids as asserted in the declaration (see page 3 and the testing results in the declaration). Other organic acids for example acetic acid, sorbic acid, and adipic acid taught by the cited prior art (see 5,460,833 col.4 lines 45-50 and 5,569,461 col.3 lines 43-47) are not alpha-hydroxy organic acids. Thus, the evidence in the examples does not demonstrate criticality of a range of the ingredients disclosed by the prior art. See MPEP § 716.02(d).

Therefore, there is no clear and convincing evidence in the declaration for supporting for the synergism produced by the instant combination over the prior art. Therefore, the declaration is insufficient to rebut the prima facie case herein.

Moreover, as discussed in the previous Office Action, Applicant's testing data and remarks regarding the results herein on the 2-part systems in the specification have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive as discussed below. The testing results on 2-part systems herein provide no clear and convincing evidence of nonobviousness or unexpected results over the prior art since the specification provides no side-by-side comparison with the closest prior art, Andrews' patent (5,460,833 or 5,569,461), in support of nonobviousness for the instant claimed invention over the prior art. It is noted that the conditions for testing on antimicrobial

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activity in Andrews are different from the conditions herein, e.g., temperature and time. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.


For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
November 7, 2003